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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,122	04/14/2004	Richard Rox Anderson	022727-0110	3121

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EXAMINER
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KARPINSKI, LUKE E

ART UNIT	PAPER NUMBER
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4173

NOTIFICATION DATE	DELIVERY MODE
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11/15/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

## Office Action Summary

**Application No.**

10/709,122

**Applicant(s)**

ANDERSON ET AL.

**Examiner**

Luke E. Karpinski

**Art Unit**

4173

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 sheets</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-34 are pending.

Claims 35-43 are canceled.

Claims 1-34 are under consideration in this action.

### **Restriction/Election**

1. Applicant's election without traverse of Invention I, drawn to a method for protecting epithelial tissue during photodynamic therapy, in the reply filed on 10/05/2007 is acknowledged. Acknowledgement is also made to the election of aminolevulinic acid for Species A, 4-dioxoheptanoic acid for Species B, and aminolevulinic acid with 4-dioxoheptanoic acid for Species C.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 4173

3. Claims 16, 20, 22, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 16 uses the language "equal to or **greater than about 25°C**". It is unclear as to whether Applicant desires the limitation to be about 25, which could be 24, or greater than 25, which could not be less than 25, as about 25 suggests.
5. Claim 24 uses the same language as claim 16 and results in the same confusion.
6. Claim 25 contains the compound name 4-dioxoheptanoic acid. Such a compound does not exist. Examiner views this as a typographical error but is unsure if Applicant meant to claim 4-oxoheptanoic acid or if Applicant meant to claim a dioxoheptanoic acid but simply neglected to specify the position of the other Oxygen molecule with another number in addition to the 4 (i.e. 4,6-dioxoheptanoic acid).
7. Claim 26 uses the language "**at least about 15 minutes**". It is unclear as to whether Applicant desires the limitation to be about 15 minutes, which could be 14 minutes, or if Applicant desires greater than 15 minutes, which cannot be 14 minutes.
8. In order to move along in the prosecution of the instant application Examiner will examine succinylacetone in place of 4-dioxoheptanoic acid. The two compounds are the most similar in structure within the group of chemical inhibitors within claim 25.
9. The Examiner will also interpret claims 16 and 24 to read greater than and claim 26 to read at least.

Art Unit: 4173

10. Claim 20 asserts that malignant cells are substantially destroyed. The term "substantially destroy" is not defined in the specification as to particularly point out to what extent the malignant cells are removed.

11. Claim 22 asserts that hair associated with hair follicles is "substantially removed". Again the term "substantially remove" is not defined in the specification as to particularly point out what amount of the hairs are removed.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the chemical inhibitors disclosed within claim 25 of the instant application, does not reasonably provide enablement for all chemical inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is unreasonable to think that any chemical inhibitor, of which there are thousands, would inhibit the metabolism of a pre-photosensitizing agent.

Art Unit: 4173

**Claim Rejections - 35 USC § 103**

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-19 and 22**

15. Claims 1-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,050,990 to Tankovich et al. in view of US Patent No. 5,709,654 to Klatz et al.

***Applicant Claims***

16. Applicant claims a method for protecting epithelial tissue during hair removal utilizing photodynamic therapy induced using a pre-photosensitizing agent. The method comprising: administering said pre-photosensitizing agent, preventing the metabolism of the pre-photosensitizing agent into a photosensitizing agent while still allowing the metabolism to occur at the desired treatment site, and irradiating the treatment site wherein the tissue surrounding the treatment site is substantially unaffected. Applicant claims the prevention of the metabolism is due to a temperature gradient between the treatment site and the surrounding tissue, which is due to either cooling the surrounding tissue, heating the treatment site, or both. Applicant claims different skin conditions that can be treated, different temperature ranges, and energy sources.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Art Unit: 4173

17. Tankovich et al. discloses:

1) Methods for protecting epithelial tissue using temperature control (col. 64, lines 58-67).

2) The topical application of aminolevulinic acid for use in photodynamic therapy (col. 39, lines 58-66).

3) Creating a temperature gradient between epithelial tissue and a targeted treatment site (col. 63, lines 59-61 and col. 64, lines 58-67).

4) Creating the gradient by cooling the skin prior to irradiation and irradiating with a laser (col. 64, lines 58-67).

5) Cooling the skin with a device containing a cooling medium, wherein the device includes a radiant energy source and at least one portion of the device is transparent, the device is couple to a light source and the cooling and irradiation take place concurrently (col. 18, lines 12-24 and col. 19, lines 38-46).

6) The epithelial tissue being cooled to a temperature that differs from that of the targeted treatment site by at least 5°C, wherein the epithelial tissue is cooled to equal to or less than 25°C and about 20°C to -5°C and the temperature gradient is created through the cooling the tissue surrounding the treatment site and heating the treatment site. The tissue at the treatment site being heated to equal to or greater than 25°C and in the range of about 25C to 40C with a radiant energy source of light (col. 3, lines 40-54).

7) Controlling tissue damage during photodynamic therapy using a chromophore to affect hair and hair ducts with skin cooling (abstract).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims***  
***(MPEP §2141.012)***

18. Tankovich et al. does not teach:

- 1) Preventing the metabolism of aminolevulinic acid to a protoporphyrin through cooling.
- 2) The cooling medium being a solid, liquid, or gas.
- 3) Removing the contact device from the skin before the step of irradiating.
- 4) Using microwave energy, ultrasound, or radiofrequency energy as the radiation source.

The deficiencies are cured by Klatz et al. and are obviated per the teachings of Tankovich and common sense. Klatz et al. cures of not teaching preventing the metabolism of aminolevulinic acid to a protoporphyrin through cooling by teaching that cooling the body sufficiently will inhibit metabolism and the production of free radicals, which cause tissue damage, will decrease (col. 4, lines 59-65 and col. 12, lines 62-65). In regards to the cooling medium being solid, liquid, or gaseous. It is common sense to one of ordinary skill in the art that a cooling medium would have to be one of the 3 forms of matter known to man. It would also be common sense to one of ordinary skill in the art that one could use any or all of the forms of matter for the use of cooling something.

***Finding of Prima Facie Obviousness Rational and Motivation***

**(MPEP §2142-2143)**

Although Tankovich et al. does not teach cooling a treatment area to prevent metabolism of a protoporphyrin precursor to a protoporphyrin it would have been obvious to a skilled artisan that to combine methods of photodynamic therapy which embrace using aminolevulinic acid with the knowledge that cooling the body down slows the process of metabolism. It was well known at the time of the invention that the body naturally metabolizes aminolevulinic acid into a protoporphyrin, and that metabolism is slowed down with lower temperatures. It was also well known at the time of the invention that irradiation of a protoporphyrin causes tissue damage but that irradiation of aminolevulinic acid does not cause tissue damage. A skilled artisan would have recognized that it would be possible to prevent unwanted tissue damage by simply cooling the area surrounding the treatment site to prevent the metabolism of aminolevulinic acid into a photosensitive compound before irradiating the area intended for treatment.

20. In regards to removing the contact device from the skin before the irradiating step. It would have been common sense to one of ordinary skill in the art to remove any device from between an area to be irradiated and the irradiation source.

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tankovich et al. with Klatz et al. The motivation comes from the fact that both are from the same area of endeavor, of protecting tissue

Art Unit: 4173

from damage due to free radicals and each teaches methods of cooling tissue, which inhibits free radical production.

22. In regards to using microwave energy, ultrasound, or radiofrequency energy as the radiation source. It would have been obvious to a skilled artisan that any of these forms of radiant energy could be used for the purpose of heating tissue. It is well known that one can use visible light, infrared light, microwave energy, ultrasound, or radiofrequency energy to transfer heat. It would have been obvious to a skilled artisan to use any safe available heat source to heat tissue.

24. The motivation to combine the references is in the fact that both references are in the same field of endeavor, which is to protect tissue from damage through temperature control of tissue. There was also a reasonable expectation of success in combining the references due to the fact that one reference teaches a photodynamic treatment, which was well known at the time and the other reference simply teaches the effect of temperature on the metabolism of aminolevulinic acid.

#### ***Claims 20-21***

14. Claims 1, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,050,990 to Tankovich et al. as applied to claim 1 above, and further in view of US Patent No. 5,955,490 to Kennedy et al. .

***Applicant Claims***

26. Applicant claims all of the limitations recited above in the instant office action as well as the targeted treatment site comprising of malignant cells or sebaceous glands.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

27. Tankovich et al. and Klatz et al. disclose all of the limitations recited above in the instant office action in addition to the use of a laser for the methods disclosed by Tankovich et al.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

28. Neither Tankovich et al. nor Klatz et al. teach the treatment site comprising of malignant cells or sebaceous glands.

Kennedy et al. cures the deficiency of Tankovich et al. And Klatz et al. through teaching that photodynamic therapy can be used to treat malignant cells (col. 4, lines 63-64) as well as sebaceous glands (col. 18, lines 3-9).

30. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tankovich et al., Klatz et al., and Kennedy et al. to use the methods disclosed in Tankovich et al. to treat malignant cells as well as sebaceous glands.

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

The deficiencies of Tankovich et al. and Klatz et al. are overcome by Kennedy et al. because all references are in the field of photodynamic therapy and even though Tankovich et al. and Klatz et al. do not teach the treatment of malignant cells or sebaceous glands Kennedy et al. teaches that photodynamic therapy was known to be used for the treatment of malignant cells and sebaceous glands.

31. The motivation to combine Tankovich et al. and Klatz et al. with Kennedy et al. is in the fact that both references are in the same field of endeavor, which is using photodynamic therapy for the use in treating skin conditions. They both also teach using aminolevulinic acid as a pre-photosensitizing agent with which to treat said skin conditions. The motivation to combine Tankovich et al. with Klatz et al. is discussed above. There was a reasonable expectation of success at the time to combine the teachings of Tankovich et al., Klatz et al., and Kennedy et al. because Kennedy et al. does nothing more than teach different types of skin conditions that may be treated with the disclosed method and the type of site has no bearing on the fact that the method causes tissue damage to the targeted site.

**Claims 23-34**

15. Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,050,990 to Tankovich et al. as applied to claim 1 above, and further in

Art Unit: 4173

view of US Patent No. 5,114,973 to Hess et al. and US Patent No. 5,955,490 to Kennedy et al.

### ***Applicant Claims***

33. Applicant claims all of the limitations recited above in the instant office action as well as a chemical inhibitor being incorporated into a topical cream at certain percentage amounts and the application of the cream to a patients skin, simultaneously and at times differing from that of the application of the pre-photosensitizing agent. Applicant also claims a specific pre-photosensitizing agent.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

34. Tankovich et al. discloses all of the limitations recited above in the instant office action.

1) Succinylacetone as an inhibitor of aminolevulinic acid (col. 1, lines 60-63).

### ***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

35. Tankovich et al. et al. does not disclose:

1) Topical application.

2) A chemical inhibitor concentration of greater than 0.1%.

Art Unit: 4173

- 3) The chemical inhibitor within a cream.
- 4) Application in conjunction with a pre-photosensitizing agent.
- 5) Aminolevulinic acid at a concentration of at least 0.1%.
- 6) Applying a chemical inhibitor and cooling the tissue to be treated.
- 7) The chemical inhibitor application having duration of at least 15 minutes.
- 8) A chemical inhibitor of the metabolism of a prephotosensitizing agent.

These deficiencies are cured by the following references or obviated by the teachings of Tankovich et al. together with knowledge commonly known in the art.

Kennedy et al. cures the deficiency of Tankovich et al. through the teaching of aminolevulinic acid at a concentration of at least 0.1% (col. 20, lines 49-54).

Hess et al. cures the deficiency of Tankovich et al. through the teaching of succinylacetone being an inhibitor of the second enzyme of the heme biosynthetic pathway, which is aminolevulinic acid.

***Finding of Prima Facie Obviousness Rational and Motivation***  
**(MPEP §2142-2143)**

The deficiency in the teachings of Tankovich et al. is cured due to the fact that Kennedy et al. teaches the limitation of a specific concentration for aminolevulinic acid. Even though Kennedy et al. does not teach specifically 0.1%, it is common in the art that experimentation is undertaken in order to optimize the specific concentration of ingredients in a composition. The deficiency of Tankovich not teaching a chemical inhibitor of a pre-photosensitizing agent is cured by Hess et al. simply by the fact that Hess et al. discloses that succinylacetone is an inhibitor of aminolevulinic acid.

Art Unit: 4173

37. It would have been obvious at the time of the invention to combine the teachings of Tankovich et al., Klatz et al., Hess et al., and Kennedy et al. to use a chemical inhibitor to prevent the metabolism of a pre-photosensitizing agent in order to prevent damage to tissue surrounding a site being treated with photodynamic therapy. The motivation to combine Tankovich et al., Klatz et al., and Kennedy et al. is given above in the instant office action. Any skilled artisan dealing with photodynamic therapy and aminolevulinic acid would have been familiar with the biosynthetic pathway of heme, which is how the body transforms aminolevulinic acid into a photosensitive agent. The motivation to combine Tankovich et al. and Kennedy et al. with Hess et al. is the fact that Tankovich et al. and Kennedy et al. are both in the same field of endeavor, being photodynamic therapy, and Hess et al. teaches inhibitors to aminolevulinic acid, which is a common pre-photosensitizing agent, and is a common compound used in photodynamic therapy as disclosed within Kennedy et al.

38. It would have been obvious to one of ordinary skill in the art at the time of the invention to use both methods of inhibiting metabolism of a pre-photosensitizing, cooling the tissue and applying a chemical inhibitor, in order to prevent tissue damage. It is common in the medical field to use more than one method of treatment at the same time.

39. In regards to topical application of a chemical inhibitor within a cream, it would have been obvious to a skilled artisan at the time of the invention to apply the chemical inhibitor directly onto the tissue surrounding the treatment site. It also would have been

Art Unit: 4173

obvious to apply the inhibitor in the form of a cosmetic cream, for ease of application because creams are conventional forms of topical compositions.

40. In regards to the concentration of about 0.1%, it would have been obvious to a skilled artisan that to be present in any composition the chemical inhibitor would need to have some concentration value and it is common in the art that experimentation is undertaken in order to optimize the specific concentration of ingredients in a composition.

41. In regards to the chemical inhibitor application having duration of at least 15 minutes, it would have been obvious to one of ordinary skill in the art that the irradiation process would take at least 15 minutes and that the chemical inhibitor should remain on the tissue throughout the duration of the irradiation process.

42. The motivation to combine the teachings of Hess et al. with those of Tankovich et al. and Kennedy et al. is that Hess teaches inhibitors to aminolevulinic acid while the others teach the use of aminolevulinic acid for photodynamic therapy. There would have been a reasonable expectation of success in combining these references due to the fact that Tankovich et al. and Kennedy et al. cover photodynamic therapy methods and Hess et al. covers properties of a pro-drug that is commonly used in the photodynamic therapy art.

Art Unit: 4173

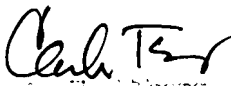
***Inquiries***

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke E. Karpinski whose telephone number is 571-270-3501. The examiner can normally be reached on Monday Thursday 9-4 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin H. Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

  
Charles Tsang  
Supervisor  
Art Unit 4173  
Patent Office  
October 10, 2010